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510(k) Summary

As required by section 807.92(c)

Company Name	Cardiosolutions Inc.
Address	375 West St. West Bridgewater MA 02379 Phone: 781-344-0801 Fax: 781-344-0803
Contact Person	Michele Lucey
Date Prepared	April 24, 2012
Trade Name	Percu-Pro™ Steerable Introducer
Common Name	Steerable Introducer
Classification Name	Steerable Guide Catheter
Product Code	DRA, DYB
Regulation #	21 CFR 870.1280
Class	2
Panel	Cardiovascular
Predicate Devices	St. Jude Medical, Diag Division, Inc., Agilis™ Steerable Catheter Introducer, K042623 Evalve Inc., Steerable Guide Catheter, K100789
Device Description	The Cardiosolutions Percu-Pro™ Steerable Introducer is a 14Fr Introducer. The set also consists of a dilator, stylet, and tear-away introducer sheath. The steerable introducer is designed to provide flexible catheter positioning in the cardiac anatomy. The steerable introducer provides both proximal tip and distal tip steering and is fitted with a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A sideport with stopcock is provided for air or blood aspiration, fluid infusion, blood sampling, and pressure monitoring. The introducer sheath is reinforced Pebax and the distal tip has a radiopaque marker to improve fluoroscopic visualization. The device is provided in 65 cm or 80 cm working lengths. The device is provided sterile and is intended for single use only.
Intended Use	The Percu-Pro™ Steerable Introducer is intended to be used for the introduction of various cardiovascular catheters into the heart, including the left side of the heart through the inter-atrial septum.
Safety and Performance Testing	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices, However, testing was conducted in accordance with protocols based on the requirements of industry standards and guidance

	documents. Safety and performance testing included: Biocompatibilty and Hemocompatibility testing in accordance with ISO 10993 were conducted. Results demonstrate that the device is suitable for its intended use. The assessments performed include: Cytotoxicity o Systemic Injection o Intracutaneous Injection No intracutaneous reaction observed o Sensitization Maximization o Material Mediated Pyrogenicity o Direct Hemolysis o Partial Thromboplastin Time o In Vivo Thromboresistance Study in Dog* o ASTM Hemolysis- Direct Contact o SC5b-9 Complement Activation Assay o C3a Complement Activation Assay Mechanical testing was conducted in accordance with the ISO 10555 Sterile, single-use intravascular catheters Part 1: General requirements (as amended, 1999, 2004) and in consideration of FDA Guidance on Premarket Notification 510(k) Submission for Short Term and Long Term Intravascular Catheters. The following tests were completed: o Visual Surface Inspection o Dimensional Verification o Corrosion Resistance o Tensile Break Force o Tip Separation Force o Freedom from Leakage Under Pressure o Air Leakage During Aspiration o Luer Hub Compliance o Flexural Fatigue Tolerance o *In Vitro* Simulated Use Studies o Functional Performance Testing o Radiopacity All test results demonstrate that the properties and performance of the device are suitable for its intended use.
Substantial Equivalence	The Percu-Pro™ Steerable Introducer is substantially equivalent to the predicate devices in terms of intended use, design, materials, technology, and function. There are no differences between devices which would raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 2 4 2012

Cardiosolutions, Inc.
c/o Ms. Michele Lucey
Vice President, Regulatory Affairs & Quality Assurance
375 West Street
West Bridgewater, MA 02379

Re: K120086
Trade/Device Name: Percu Pro Steerable Introducer
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable Guide Catheter
Regulatory Class: Class II
Product Code: DRA, DYB
Dated: March 9, 2012
Received: March 12, 2012

Dear Ms. Lucey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120086

INDICATIONS FOR USE

510(k) Number (if known): K120086

Device Name: Percu-Pro™ Steerable Introducer

Indications for Use:

The Percu-Pro™ Steerable Introducer is intended to be used for the introduction of various cardiovascular catheters into the heart, including the left side of the heart through the inter-atrial septum.

Prescription Use ___X___ AND/OR Over-The_Counter Use_____

(PLEASE DO NOTR WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120086